

HATCHERY
34 LUDLAM AVENUE
BAYVILLE, NY 11709
TEL: 516-628-2077
FAX: 516-628-3402

FRANK M. FLOWER & SONS INC.

P.O. BOX 88
OYSTER BAY, NY 11771-0088

GROWERS OF PINE ISLAND OYSTERS

OFFICE AND DOCK
2 BAYVIEW AVENUE
OYSTER BAY, NY 11771
TEL: 516-922-4410
FAX: 516-922-4744

0306 '99 APR 26 AM 10:40

April 20, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

To USFDA:

Frank M. Flower and Sons Inc. has been in the shellfish business since 1887. We currently employ 40 people and some years we produce as much as 90% of New York State's oysters. Hard clams also constitute a considerable part of our output. We have a 5000 sq. ft. shellfish hatchery which supplies the oyster and clam seed that we plant on underwater lands which we lease from the Town of Oyster Bay. We have 4 historic oyster boats and 2 modern suction dredges which range from 50-90 ft. in length. Those boats are used to farm and harvest our aquaculturally raised products.

Virtually all of the oysters and clams we sell are consumed raw. For that reason we are particularly concerned with your notice in the Federal Register concerning *Vibrio vulnificus* (Vv). A nondetectable performance standard would put us out of business because any post harvest treatment that is now available kills the shellfish and changes the texture and flavor of the product. We believe that the consumer will reject this "cooked" product as was evidenced by its brief introduction to the New York Market.

Is this nondetectable performance standard really necessary? Vv illnesses have occurred mostly as a result of Gulf Coast oysters under summer conditions. Only 15-20 individuals per year are affected out of 30 million at risk (with compromised immune systems). The infective level of Vv must be determined and used as a performance standard only in Gulf Coast States which have been associated with Vv illnesses. Shellfish other than oysters have not been associated with Vv illness, thus there is no reason to consider a standard for those products.

Vibrio parahaemolyticus (Vp) infections are not lethal and should not be considered like Vv. The Interstate Shellfish Sanitation Conference (ISSC) has an Interim Control Plan (ICP) to address the Vp problem. Hopefully, the infective level of the Asian 03K6 strain will soon be found and new standards for the ICP will be established at the July meeting of the ISSC including more definitive criteria for reopening growing areas closed by Vp. Many other *Vibrio* species are found in all shellfish at all times of the year. Standards should not be set for them until such time that they are identified.

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as causing illnesses.

Notification and education of the at risk population has been helpful and must be continued and improved. Ultimately the ISSC will come up with guidelines which will better ensure public health without destroying the tradition of eating raw shellfish.

Sincerely:

A handwritten signature in black ink, reading "David R. Relyea". The signature is fluid and cursive, with a large initial "D" and a long, sweeping underline.

David R. Relyea
Co-Owner

FRANK M. FLOWER & SONS, INC.

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(DOCKET NO.)
98P-0504

DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE, RM. 1061
ROCKVILLE, MD 20852

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